08-6079 01-480404

> Superior Court Civil Bowie, Cheryl vs. Medtronic Inc 3AN-08-06079CI

IN THE

TRIAL COURTS

PLAINTIFF'S ATTORNEY

OF THE

STATE OF ALASKA

TYPE OF PROCEEDING

MASTER ASSIGNED

DATE ASSIGNED

DATE DISQUALIFIED

BY WHOM DISQUALIFIED

DEFENDANT'S ATTORNEY

EXHIBIT of 16 PAGE

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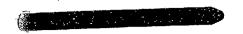
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IN THE IN THE STATE OF ALASKA AT ANCHORAGE

AT ANCHORAGE		
CHERYL BOWIE,		
Plaintiff(s), vs. MEDTRONIC INC. REGENERATION TECHNOLOGIES, INC., SPINALGRAFT TECHNOLOGIES, GALEN HOSPITAL ALASKA, INC. d/b/a ALASKA REGIONAL HOSPITAL and BIOMEDICAL TISSUES SERVICES, LTD.) Defendant(s). Defendant(s). SUMMONS AND NOTICE TO BOTH PARTIES OF JUDICIAL ASSIGNMENT		
To Defendant: BIOMEDICAL TISSUES SERVICES, LTD.		
You are hereby summoned and required to file with the court a written answer to the complaint which accompanies this summons. Your answer must be filed with the court at 825 W.4th Ave., Anchorage, Alaska 99501 within 20 days* after the day you receive this summons. In addition, a copy of your answer must be sent to the plaintiff's attorney, Richard A. Helm of Bookman & Helm, LLP whose address is: 471 W. 36th Ave., Suite 204, Anchorage, AK 99503		
If you fail to file your answer within the required time, a default judgment may be entered against you for the relief demanded in the complaint.		
NOTICE OF JUDICIAL ASSIGNMENT		
TO: Plaintiff and Defendant		
You are hereby given notice that: This case has been assigned to Superior Court Judge		
Plaintiff(s), VS. AEDTRONIC INC. REGENERATION IECHNOLOGIES, IRC. SPINALGRAFT ECHNOLOGIES, GALEN ROSPITAL ALASKA, INC. d/b/a ALASKA RECIONAL HOSPITAL and BIOMEDICAL TISSUES SERVICES, LTD. Defendant(s). SUMMONS AND NOTICE TO BOTH PARTIES OF JUDICIAL ASSIGNMENT To Defendant: BIOMEDICAL TISSUES SERVICES, LTD. You are hereby summoned and required to file with the court a written answer to the complaint which accompanies this summons. Your answer must be filed with the court at 825 W. 4th Ave., Anchorage, Alaska 99501 within 20 days* after the day you receive this summons. In addition, a copy of your answer must be sent to the plaintiff's attorney. Richard A. Helm of Bookman & Helm, LLP whose addressis: 471 W. 36th Ave., Suite 204, Anchorage, AK 99503 If you fail to file your answer within the required time, a default judgment may be entered against you for the relief demanded in the complaint. NOTICE OF JUDICIAL ASSIGNMENT TO: Plaintiff and Defendant You are hereby given notice that:		
CLERK OF COURT Solver Tries By: Deputy Clerk CLERK OF COURT Deputy Clerk		

^{*} The State or a state officer or agency named as a defendant has 40 days to file its answer.

IN THE INIXIAN SUPERIOR COURT FOR THE STATE OF ALASKA AT ANCHORAGE

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CHERYL BOWIE,) Plaintiff(s),	
vs. MEDTRONIC, INC. TECHNOLOGIES, I TECHNOLOGIES, G INC. d/b/a ALAS and BIOMEDICAL	REGENERATION NC., SPINALGRAFT ALE, HOSPITAL ALASKA,) KA REGIONAL HOSPITAL, KA REGIONAL HOSPITAL, TISSUES SERVICES, LTD), Defendant(s).	CASE NO. 3AN- 08-6079C/ SUMMONS AND
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To Defendant:	and required to file with the c	court a written answer to the complaint which with the court at 825 W. 4th Ave., Anchorage,
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If you fail to file you for the relief	your answer within the required time demanded in the complaint.	e, a default judgment may be entered against
	NOTICE OF JUDICIAL	ASSIGNMENT
TO: Plaintiff an	d Defendant	
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CTV-100 ANCH (6/99)(st.3) SUMMONS Civil Rules 4, 5, 12, 55

IN THE DISTRICTIVES AT ANCHO	T FOR THE STATE OF ALASKA ORAGE
CHERYL BOWIE,	
Plaintiff(s), VS. MEDTRONIC INC., REGENERATION TECHNOLOGIES, INC., SPINALGRAFT TECHNOLOGIES, GALEN HOSPITAL ALASKA, TECHNOLOGIES, GALEN HOSPITAL, INC. d/b/a ALASKA REGIONAL HOSPITAL, INC. d/b/a ALASKA REGIONAL HOSPITAL, and BIOMEDICAL TISSUES SERVICES, LTD. Defendant(s).	CASE NO. <u>3AN- 08- (2079</u> CI SUMMONS
	AND NOTICE TO BOTH PARTIES OF JUDICIAL ASSIGNMENT
To Defendant: SPINALGRAFT TECHNOLOGI	ES
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TO: Plaintiff and Defendant	IND ROOKSIN DELL
You are hereby given notice that: This case has been assigned to Superior Cou	rt Judge <u>CHASC</u>
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Date Date	PAGE 4 OF 16

* The State or a state officer or agency named as a defendant has 40 days to file its answer.

CTY-100 ANCH (6/99)(st.3) SUMMONS

Civil Rules 4, 5, 12, 55

PAGE

IN THE DESCRIPTION COURT FOR THE STATE OF ALASKA AT ANCHORAGE

CHERYL BOWIE,	
Plaintiff(s),)))
MEDTRONIC INC., REGENERATION TECHNOLOGIES, INC., SPINALGRAFT TECHNOLOGIES, GALEN HOSPITAL ALASKA, INC. d/b/a ALASKA REGIONAL HOSPITAL, and BIOMEDICAL TISSUES SERVICES, LTD. Defendant(s).	CASE NO. 3AN- 08-6079C(SUMMONS AND NOTICE TO BOTH PARTIES OF JUDICIAL ASSIGNMENT
To Defendant:REGENERATION_TECHNOLO	
accompanies this summons. Your answer must be	th the court a written answer to the complaint which e filed with the court at 825 W. 4th Ave., Anchorage, receive this summons. In addition, a copy of your Richard Helm of Bookman & Helm, LLP ite 204, Anchorage, AK 99503
	ed time, a default judgment may be entered against
NOTICE OF JUD	ICIAL ASSIGNMENT
TO: Plaintiff and Defendant	
You are hereby given notice that: This case has been assigned to Superior Co	ourt Judge CCCCC
This case has been assigned to District Co	urt Judge
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* The State or a state officer or agency named	as a defendant has 40 days to file its answer. Civil Rules 4, 5, 12, 55
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IN THE BISHARDA ANCHORAC	BE .
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CHERYL BOWIE, Plaintiff(s), VS. MEDTRONIC, INC., REGENERATION TECHNOLOGIES, INC., SPINALGRAFT TECHNOLOGIES, GALEN HOSPITAL ALASKA, INC. d/b/a ALASKA REGIONAL HOSPITAL, INC. d/b/a ALASKA REGIONAL Defendant(s). and BIOMEDICAL TISSUES SERVICES, LTD.,	CASE NO. <u>3AN- 08- UCH</u> CI SUMMONS AND NOTICE TO BOTH PARTIES OF JUDICIAL ASSIGNMENT
MEDTRONIC, INC.	
To Defendant: You are hereby summoned and required to file with the confidence of the confidence of the summons. Your answer must be filed within 20 days* after the day you receive answer must be sent to the plaintiff's attorney, Richard and Richar	rthis summons. In addition, a copy of your rd Helm of Bookman & Helm, LLP 04, Anchorage, AK 99503
If you fail to file your answer within the required time, you for the relief demanded in the complaint.	a default judgment may be entered against
NOTICE OF JUDICIAL	ASSIGNMENT
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You are hereby given notice that: This case has been assigned to Superior Court Ju	dge CHEASCA.
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Date Date	CLERK OF COURT By: Deputy Clerk EXHIBIT A defendant has 40 days to file its answer. Civil Rules 4, 5, 12, 55
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	Civil Rules 4, 5, 12, 55



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NAME Richard A. Helm, Esq. Bookman & Helm, LLP	471 W. 36th Av Anchorage, AK	7e. Suite 204 99503 865-0800	Plaintiff
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REAL PROPERTY Foreclosure (CISFOR) Condemnation (CISCNE) Real Property Action (CI	oM)	Support Order (CIPCS Petition for Order re: P (CIPND) Retablishment of Pater) PFD or Native Dividend nity (CISPAT)
OTHER CIVIL Arbitration Proceeding (CISAP) Confession of Judgment (CISCCONF) Declaratory Judgment/Injunc. Relief (CISINJ) OSC Request – Admin Agency (CIOSC) Civil Bench Warrant Request – Admin Agency (CIBW)		or Enforcement) (DR4 Foreign Support Order or Enforcement) (CIU	r (Registration, Modification (Registration, Modification (IFSA) In Domestic Relations Order
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Writ of Habeas Corpus Election Contest or Rec Other Civil Complaint	(CISOCI). Describe:		PAGEOF

CIV-125S (CourtView version) (3/05)(cs duplex)

CASE DESCRIPTION - SUPERIOR COURT

Case Number:	3AN-08-4079	<u>CI</u>

Check the box that best describes the case. Mark one box only. For district court cases, use form CIV-125D.

SUPERIOR COURT MATTERS			
CIVIL - SUPERIOR COURT	FORCIBLE ENTRY AND DETAINER - SUPERIOR COURT		
CONTRACT – Contract cases involving real property	Eviction – F.E.D. (CISFED)		
should be reported under the real property category. Debt Collection (CISDEB) Claim Against Seller of Goods/Services	FOREIGN JUDGMENT – SUPERIOR COURT Registration of Foreign Judgment (CISFOJ)		
(CISCLAIM) Employment Dispute (CISEMP) Other Contract (CISOCT)	POST-CONVICTION RELIEF TO SUPERIOR COURT Post-Conviction Relief (CISPCR)		
TORT Intentional Tort (e.g., assault, battery, vandalism) (CISIT)	DOMESTIC RELATIONS		
Slander/Libel/Defamation (CISSLD)	DIVORCE WITHOUT CHILDREN		
Product Liability (CISPL) Wrongful Death (CISPID)	Divorce Without Children (CISDIV)		
Automobile Negligence:	DIVORCE OR CUSTODY WITH CHILDREN		
Personal Injury Only (CISPIA) Property Damage Only (CISPDA) Both (CISIDA)	Petition for Custody (CISCUS) Divorce With Children (CISDVC)		
Other Negligence: Personal Injury Only (CISPIO) Property Damage Only (CISPDO) Both (CISIDO)	LEGAL SEPARATION Legal Separation With Children (CICLS) Legal Separation Without Children (CISLS)		
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MALPRACTICE Legal Malpractice (CISLMP) Medical Malpractice (CISMMP) Other Malpractice (CISOMP) REAL PROPERTY Foreclosure (CISFOR) Condemnation (CISCNDM) Real Property Action (CISREM) OTHER CIVIL	Ex Parte Application for OSC for Failure to Comply with Admin Order for Genetic Testing (CIOSCP) Action to Modify or Enforce Administrative Child Support Order (CIPCS) Petition for Order re: PFD or Native Dividend (CIPND) Establishment of Paternity (CISPAT) Disestablishment of Paternity (CIDPAT) Foreign Custody Order (Registration, Modification		
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CIV-125S (CourtView version) (3/05)(cs duplex) CASE DESCRIPTION FORM – SUPERIOR COURT

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Other Superior Court Petition (CISPET).			
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Employment Security Appeal (CIADRESA)			
APPEAL FROM DISTRICT COURT			
Civil or Small Claims Appeal (CIACI)			
Criminal Merit Appeal (CIACRM) Criminal Sentence Appeal (CIACRS)			
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CIV-125S (CourtView version) (3/05)(cs duplex) CASE DESCRIPTION FORM – SUPERIOR COURT

BOOKMAN & HELM, LLP Attorneys At Law 471 W. 36" Avenue, Suite 204 Anchorage, AK 99533 Telephone: (907) 865-3800 Facsimile: (907) 279-4851

SUPERIOR COURT MATTERS

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

CHERYL BOWIE,

Plaintiff,

vs.

MEDTRONIC, INC., REGENERATION TECHNOLOGIES, INC., SPINALGRAFT TECHNOLOGIES, GALEN HOSPITAL ALASKA, INC. d/b/a ALASKA REGIONAL HOSPITAL, and BIOMEDICAL TISSUES SERVICES, LTD.,

Defendants.

Case No. 3AN-08-

COMPLAINT

Plaintiff alleges:

- Plaintiff, Cheryl Bowie, is a resident of Anchorage, Alaska.
- 2. Defendant, Medtronic, Inc. ("Medtronic"), is a foreign corporation doing business in Alaska.
- 3. Defendant, Regeneration Technologies, Inc. ("RTI"), is a foreign corporation doing business in Alaska.
- 4. Defendant, Spinalgraft Technologies ("SGT"), is a foreign corporation doing business in Alaska.
- 5. Defendant, Galen Hospital Alaska, Inc., is a foreign corporation doing business in Alaska, with its principal place of business in Alaska, doing business as Alaska Regional Hospital.
- 6. Defendant, Biomedical Tissues Services, Ltd. ("BTS"), is a foreign corporation doing business in Alaska.
- 7. An allograft is a human bone or tissue based product obtained from a cadaver and transplanted into a living person for medical reasons.
- 8. Common types of allograft products are made up using bone, tissue, skin, tendons, heart valves and corneas.

 EXHIBIT A

BOOKMAN & HELM, LLP Attorneys At Law 471 W. 36" Avenue, Suite 204 Anchorage, AK 99503 Telephone: (907) 865-0800 Facsimile: (907) 279-4851

- 9. BTS was formed by an oral surgeon, who had lost his oral surgery license, and a master embalmer for the purpose of harvesting human tissue, bones and organs from human corpses for resale to commercial human tissue, bone and organ processors and resellers.
- 10. Shortly after opening its business, BTS began harvesting tissue and bones from human corpses improperly obtained from various funeral homes and possibly from local city morgues in cases in which the bodies were unclaimed or unidentified.
- BTS acted as a tissue recovery agent for RTI and Medtronic, providing tissue from cadavers to RTI for processing into allografts. RTI and Medtronic, its parent company, were aware that BTS was not certified by the American Association of Tissue Banks ("AATB") and was not properly licensed as a recognized blood and/or tissue bank.
- Many of the deceased individuals whose corpses were obtained by BTS never intended to be donors or, if they did, they did not give consent to have their bones removed with the correct authorization, and their families did not authorize the use of their bodies for human bone harvesting or later transplantation.
- To circumvent obtaining the proper release from the families of the dissected corpses, BTS secretly dissected the bodies, removed the allograft materials and prepared them for burial without notifying family members of the removal. Many such dissections included replacement of harvested bone with foreign objects such as PVC piping and other objects, so that the bodies would appear normal for pending visitations, funeral or post-mortem proceedings.
- 14. BTS also altered the medical records, death certificates and identities of the corpses to conceal the lifestyle and medical or disease histories, the age of the corpses, as well as how the corpses had been treated following death. Thus, they harvested and sold tissue or bone for implantation from corpses which were not qualified for implantation.

Complaint

Bowie v. Medtronic, et al.

Case No. 3AN-08- Cl

Page 2 of 7

exhibit__A___ page__//_of_/6__

- 15. BTS illegally dissected scores of human corpses harvesting millions of dollars worth of human bones and tissue pursuant to existing contracts and/or relationships with defendants, RTI, Medtronic and SGT, for processing, manufacturing and distribution, throughout the United States.
- 16. On February 22, 2006, the principals behind BTS were indicted by the Supreme Court of Kings County (Brooklyn), New York for activities related to the issues raised in this complaint.
- 17. RTI, directly and through its partners, affiliates, agents or servants, holds itself out to the public as a business engaged in the processing, sale, promotion, marketing, harvesting, testing, procurement, preservation and distribution of manufactured products for medical use and implantation in the human body to hospitals, physicians and surgery centers nationwide and specifically in the state of Alaska. RTI markets its allograft products to health care providers and the general public with assurances of safety, fitness and merchantability.
- 18. RTI stated on its website that "[a]ll donor tissue must meet strict criteria to be released for implantation. In addition to serological and medical screening, high risk behavior is also evaluated. RTI performs multiple reviews, including: Behavior/Lifestyle Risk Assessment; Family/Next of Kin Interview; Medical Record Evaluation/Hospital Records; Medical Examiner/Coroner's Report; Medical/Social History Evaluation."
- 19. RTI failed to follow its touted required practices and procedures to assure the safety and suitability of its allograft material obtained from BTS and as a result caused nationwide distribution and implantation of illegally obtained and/or improperly processed and manufactured allografts, unsuitable allograft bone implants, including one into plaintiff.
- 20. The internal procedures of RTI, which are based on industry standards and governmental regulations, require that it ensure that donors meet strict criteria before allografts are obtained and released for implantation. The internal procedures of RTI require that it conduct stringent blood tests, a careful analysis of medical records, medical history, coroner reports and lifestyle screening to determine donor behavior and potential lifestyle risks and an interview with

Complaint

Bowie v. Medtronic, et al.

Case No. 3AN-08- CI

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a donor's next of kin or other family members to confirm the overall health and lifestyle of the donor. Also, RTI's protocol and standards require it to confirm the donor or family member's consent to bone and/or tissue removal after death.

- 21. RTI's sterilization processes were tested and studied only by RTI. The process was never approved by the FDA.
- 22. All defendants failed to use reasonable scientific procedures to detect any defects in the allograft involved in this case.
- 23. According to its processing protocol, the Medical Director of RTI will not approve any allograft source until all these procedures have been followed.
- 24. In its marketing and promotional materials, RTI represented to the public and plaintiff that its products underwent the above-described processes, which it claimed constituted redundant and stringent tissue testing and sterility procedures to ensure product safety and integrity.
- 25. RTI marketed and promoted that the source of all of the allografts was bone and tissue that had been donated by people upon their death, with the consent of either the deceased or of the deceased's family or loved ones.
- 26. RTI marketed and promoted that its screening and testing methods exceeded those required by the FDA and AATB.
- 27. Defendants failed to obtain proper consent from donors in violation of various rules, laws, regulations and industry standards.
- 28. RTI and Medtronic knew or should have known that BTS was not certified by the AATB and thus, given industry practice standards were on notice to provide even more detailed scrutiny to BTS supplied bone and tissue, paperwork and donor records.
- 29. Medtronic and RTI formed a joint venture in the early 2000's whereby Medtronic was the primary or sole distributor of RTI allograft products, thus increasing the market for RTI products. Medtronic was to receive up to 75% of all revenue from the sale of RTI allografts, as a commission.

Complaint *Bowie v. Medtronic, et al.* Case No. 3AN-08- Cl

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BOOKMAN & HELM, LLP
Attorneys At Law
471 W. 36" Avenue, Suite 204
Anchorage, AK 99503
Telephone: (907) 865-0800
Facsimile: (907) 279-4851

- 30. Medtronic, in violation of industry standards, governmental regulations, including, but not limited to, their own internal safety and testing procedures and applicable laws, processed, designed, manufactured and distributed allografts from large quantities of bone they acquired from BTS to ARH.
- 31. Plaintiff and plaintiff's surgeon was not aware that the allograft. later recalled, consisted of stolen or improperly obtained human bone obtained by BTS, RTI and Medtronic, or that RTI and Medtronic failed to follow required safety protocols, applicable governmental law and regulations and/or other industry standards.
- 32. On December 22, 2004, plaintiff underwent anterior disk excision, osteophyte removal and instrumented anterior fusion with cornerstone allograft and premier instrumentation components, C5-6, C6-7, performed by Dr. Kralick at ARH. This consisted of two allografts, which were sold by ARH. The allografts were supplied by Medtronic or one of its subsidiaries and RTI.
- 33. Sometime after December 22, 2004, one of the allografts placed in plaintiff was recalled. Plaintiff was not notified of the recall.
- 34. Plaintiff's recovery following the December 22, 2004 procedure was not good. On April 6, 2006, plaintiff underwent another operation on her cervical spine and it was discovered that one of the allografts had virtually dissolved. At this time, plaintiff was unaware that this allograft had been recalled. This operation was necessitated by the failed allograft.
 - 35. Plaintiff learned that one of her allografts had been recalled in January 2007.
- 36. On January 30, 2007, plaintiff underwent another extensive operation using both anterior and posterior approaches to repair and correct the damage caused by the failed allograft and by the 2006 surgery which was necessitated by the failed allograft.
- 37. Plaintiff may have been exposed to HIV-1, HIV-2, AIDS or hepatitis by the recalled allograft and should undergo testing for the rest of her life.

EXHIBIT A

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Complaint

Bowie v. Medironic, et al.

Case No. 3AN-08- CI

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BOOKMAN & HELM, LLP Altorneys At Law 471 W. 36" Avenuc, Suite 204 Anchorage, AK 99503

Felephone: (907) 855-0800 Facsimile: (907) 279-4851

- 38. Plaintiff has experienced emotional distress as a result of learning that a stolen and improperly processed bone was placed in her body.
- 39. Defendants, Medtronic and RTI, have offered no assistance to plaintiff for her medical care and have not offered to provide testing to her to determine if she has been infected by the allograft.
- 40. On or about October 14, 2005, RTI issued a voluntary recall of all tissue it received from BTS, "as a result of information regarding the accuracy of donor screening documentation." RTI acknowledged that "a lack of assurance of donor identity as well as the risk of infectious diseases also exists."
 - 41. None of the defendants made an attempt to advise plaintiff of the recall.
- 42. On or about October 14, 2005, the FDA announced recalls of 21 products containing bone graft allografts sold by RTI, which the FDA classified as a Class 3 recall.
- 43. None of the defendants made an attempt to advise plaintiff of the FDA recall or that one of the allografts placed in her had been recalled.
- 44. In early February 2006, following an investigation, the FDA ordered that BTS close its operations.
- 45. In response to the FDA recall of allograft products harvested by BTS, which were manufactured and distributed by RTI and Medtronic, Medtronic announced a Patient Testing Program, paid for by Medtronic, to conduct laboratory blood tests on patients who had received allografts subject to the recall.
- 46. Plaintiff was not invited to participate in the laboratory tests, nor was she advised of the tests.
- 47. Medtronic provided instructions to doctors and patients that it would pay for confidential testing to be conducted at LabCorp or Quest Diagnostics for an initial blood screen for HIV, hepatitis B, hepatitis C and syphilis. Plaintiff was not advised of this.

Complaint

Bowie v. Medtronic, et al.

Case No. 3AN-08- CI

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'elephone: (907) 865-0800 Pacsimile: (907) 279-485

49. The allograft sold to plaintiff by defendants was defective. Defendants are strictly liable for this defective product.

Defendants acted with reckless disregard to the plaintiff and such conduct was 50. outrageous.

51. Defendants acted negligently.

As a result of the wrongful conduct of defendants, plaintiff has been injured. She has 52. incurred and will incur medical expenses. She has lost income and earning capacity. She has experienced and will experience pain and suffering. She has incurred mental distress as a result of not being able to adequately support her son and has had to rely on her mother.

RTI and Medtronic intentionally misrepresented to the public and to plaintiff that the 53. allografts they supplied to plaintiff were properly harvested, treated, tested and were fit for implantation, when they knew or should have known that this was not true.

WHEREFORE, plaintiff asks that she be granted judgment against the defendants and each of them for her damages in an amount in excess of \$100,000 to be proved at trial, punitive damages, for her costs, interest and attorneys' fees and for such other relief as the Court may deem just.

DATED at Anchorage, Alaska this ** day of March, 2008.

BOOKMAN & HELM, LLP Attorneys for Plaintiff, Cheryl Bowie

Richard A. Helm

Alaska Bar # 7011059

Complaint Bowie v. Medtronic, et al. Case No. 3AN-08- CI

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